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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-----------------|----------------------|------------------------------|------------------|
| 09/662,224 | 09/14/2000 | Eugene J. Alexander | STAN-144/04US 3054 EXAMINER | |
| 36806 | 7590 12/13/2005 | | | |
| IMAGING THERAPEUTICS, INC. | | | JUNG, WILLIAM C | |
| c/o KENYON & KENYON 333 W, SAN CARLOS STREET | | | ART UNIT | PAPER NUMBER |
| SUITE 600 | | | 3737 | |
| SAN JOSE, CA 95110-2731 | | | DATE MAILED: 12/13/2005 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|---|---|---|--|--|--|--|
| | 09/662,224 | ALEXANDER ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | William Jung | 3737 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period was period to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from to cause the application to become ABANDONED | l. ely filed the mailing date of this communication. 0 (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| Responsive to communication(s) filed on <u>Septe</u> This action is FINAL . 2b)⊠ This Since this application is in condition for allowar closed in accordance with the practice under E | action is non-final. nce except for formal matters, pro | | | | | |
| Disposition of Claims | | | | | | |
| 4) ⊠ Claim(s) <u>94-108 and 169-199</u> is/are pending in 4a) Of the above claim(s) is/are withdray 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) <u>94, 96, 102-108 and 169-199</u> is/are re 7) ⊠ Claim(s) <u>95 and 97-101</u> is/are objected to. 8) □ Claim(s) are subject to restriction and/or | vn from consideration. | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the of Replacement drawing sheet(s) including the correction of the option | epted or b) objected to by the Eddrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj | 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d). | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) 1) ☑ Notice of References Cited (PTO-892) 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) ☑ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11102005. | 4) Interview Summary (Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other: | | | | | |

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DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 94-108 and 169-199 have been considered but are most in view of the new ground(s) of rejection.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 94-108 and 169-199 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 of copending Application No. 09/953,373. Although the conflicting claims are not identical, they are not patentably distinct from each other because The claimed subject matter in claims 1 and 10 disclose a method of assessing cartilage damage or disease of said joint in which mapping demonstrates thickness of the diseased cartilage tissue by obtaining three dimensional mapping. The claimed subject matter, although different in words, is identical to claimed subject matter in

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current application's independent claims 94, 102, 106, 107, 169, 177, 181, 182, 184, 192, 196, and 197.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 94-108 and 169-199 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Paul et al* (US 5,320,102).

Paul et al substantially disclose all claimed features in claims 94, 102, 106, 107, 169, 177, 181, 182, 184, 192, 196, and 197. Paul et al disclose MRI imaging method obtain three-dimensional image of joint and bone where the images include healthy or normal and diseased cartilage tissue and evaluating the images about geometry such as location and size of the healthy bone and/or cartilage to assess the disease (col. 3, line 57 – col. 4, line 39; col. 8, lines 11-61). Diagnosing the disease or damage state of the bone or cartilages dictates the treatment or therapy method (col. 1, lines 37-47). Although the thickness or the depth of the cartilage layer between the knee joints in Paul et al is determined via 2D slices the, the 3D is represented by Paul et al since the volumetric representation of the knee joint is formed from series or 2D images. Therefore, the 3D evaluation of joint images are met by Paul et al.

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6. Claims 96, 171, and 186 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Paul et al* as applied to claim 94, 169, and 184 above, and further in view of *Robinson* (US 5,291,401).

Paul et al substantially disclose all claimed features in claim 96. However, Paul et al do not disclose transferring image data from one location to another for image processing and analysis such as teleradiology. Robinson teaches that the diagnostic data such as radiological images such as Paul et al's MR images of bone can be transfer to remote location for processing an analysis. Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply Robinson's teleradiology to Paul et al's medical image diagnostic method.

7. Claims 103-105, 108, 178-180, 183, 193-195, and 198 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Paul et al* as applied to claims 94, 106, 107, 169, 181, 182, 184, 196, and 197 above, and further in view of *Hunziker* (US 5,206,023).

Paul et al substantially disclose all claimed features in claims 103-105 and 108. However, Paul et al do not disclose specific method in which the treatment is carried out. Hunziker teaches that the bone diseases/damages treatment includes chondrocytes, autografting by cell adhesion promoting factor with no-human material such as chemotactic agents, artificial implantation such as composite matrix (col. 4, lien 5 – col. 6, line 30). It would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply Hunziker's treatment method to Paul et al's diagnostic method of bone and/or cartilage diseases/damages to assess the method of treatment.

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Allowable Subject Matter

8. Claims 95 and 97-101 are objected to as being dependent upon a rejected base claim, but

would be allowable if rewritten in independent form including all of the limitations of the base

claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to William Jung, Ph.D. whose telephone number is 571-272-4739.

The examiner can normally be reached on Mon-Fri 8:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 25, 2005

SUPERVISORY PATENT EXAMINER

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